201-15559A

High Production Volume (HPV) Chemical Challenge Program

Data Review and Test Plan for 2-methyl-1,3-propanediol (MPDiol® Glycol)

CAS RN 2163-42-0

August 25, 2004

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2-methyl-1,3-propanediol (CAS RN 2163-42-0)
High Production Volume (HPV) Chemical Challenge
Data Review and Test Plan

Table of Contents

Tables

Plain English Summary

This document reviews the data availability for the EPA High Production Volume (HPV) chemical endpoints (physical-chemical properties, environmental fate and pathways, ecotoxicity and human/mammalian health effects) and provides a proposed test plan for 2-methyl-1,3-propanediol (CAS Registry Number 2163-42-0). 2-Methyl-1,3-propanediol's primary uses are in the manufacture of resins and coatings (~75%) and as a solvent (~25%) in personal care products.

There is adequate information available for 2-methyl-1,3-propanediol to meet the HPV Chemical Challenge requirements for physical-chemical and environmental fate and pathway data, acute toxicity to aquatic plants, invertebrates, and fish, and the human/mammalian health endpoints of acute toxicity, repeated dose toxicity, reproductive toxicity (fertility), developmental toxicity / teratogenicity and genetic toxicity. The HPV Chemical Challenge Program requirements are met for 2-methyl-1,3-propanediol and no further testing is proposed

Test Plan

2-Methyl-2,3-Propanediol CAS RN: 2163-42-0		Information	OECD Study	GLP	Other Study	Estimation Method	Acceptable	Testing Required
STUDY		**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**	**Y/N**
PHYSICAL - CHEMICAL DATA								
2.1	Melting Point	Y	Y	Y	N	N	Y	N
2.2	Boiling Point	Y	Y	Y	N	N	Y	N
2.4	Vapor Pressure	Y	Y	Y	N	N	Y	N
2.5	Partition Coefficient	Y	Y	Y	N	N	Y	N
2.6	Water Solubility	Y	Y	Y	N	N	Y	N
ENVIRONMENTAL FATE AND PATHWAYS								
3.1.1	Photodegradation	Y	N	N	N	Y	Y	N
3.1.2	Stability in Water	Y	N	N	N	N	Y	N
3.4	Transport and Distribution	Y	N	N	N	Y	Y	N
3.5	Biodegradation	Y	Y	Y	N	N	Y	N
ECOTOXICOLOGICAL DATA								
4.1	Acute Toxicity to Fish	Y	Y	Y	N	N	Y	N
4.2	Toxicity to Daphnia	Y	Y	Y	N	N	Y	N
4.3	Acute Toxicity to Algae	Y	Y	Y	N	N	Y	N
TOXICOLOGICAL DATA								
5.1	Acute Toxicity	Y	Y	Y	Y	N	Y	N
5.4	Repeated Dose Toxicity	Y	Y	Y	N	N	Y	N
5.5	Genotoxicity *In Vitro* (Bacterial Test)	Y	Y	Y	N	N	Y	N
5.5	Genotoxicity *In Vitro* (Mammalian Cells)	Y	Y	Y	N	N	Y	N
5.8	Reproductive Toxicity	Y	Y	Y	N	N	Y	N
5.9	Development Toxicity / Teratogenicity	Y	Y	Y	N	N	Y	N

1. Introduction

This Data Review and Test Plan and accompanying Robust Summaries for 2-methyl-1,3-propanediol (MPDiol® Glycol; CAS No. 2163-42-0) were prepared by Lyondell Chemical Company (Lyondell) to meet its commitments under the United States Environmental Protection Agency HPV Challenge Program.

The purpose of this document is to identify and summarize key studies describing physical-chemical properties, environmental fate, ecotoxicity and mammalian health effects in a manner consistent with the requirements of the HPV Chemical Challenge endpoints (equivalent to OECD SIDS Level 1 data package).

Table 1. General Substance Information (Identity)

Common Name:	1-Methyl-1,3-Propanediol
CAS No.	2163-42-0
Molecular Formula:	$C_4H_9O_2$
Structural Formula:	$CH_2OH\text{-}CCH_3\text{-}CH_2OH$
Molecular Weight:	90
Physical state:	viscous liquid
Synonyms:	methyl propanediol, MPD-1P, MPDiol® Glycol

2. Sources and Levels of Exposure

2.1 Production

2-Methyl-1,3-propanediol is manufactured by hydroformylation of allyl alcohol (2-propen-1-ol, CAS RN 107-18-6) with carbon monoxide and hydrogen to the intermediate hydroxymethylpropionaldehyde, followed by hydrogenation. It is produced by Lyondell Chemical Company at sites in the United States and the Netherlands, and marketed under the commercial trade name of MPDiol® Glycol. A second manufacturer of 2-methyl-1,3-propanediol, Dairen, operates in Taiwan. The total annual production of 2-methyl-1,3-propanediol in the US and Europe is estimated to be 50 million pounds.

2.2 Use

2-Methyl-1,3-propanediol (MPDiol® Glycol) is used as a solvent glycol (~25%) in personal care products (neutralizer, emollient, emulsifier, and humectant) as well as in the manufacture of resins and coatings (~75%). In the latter application, the two primary hydroxyl groups react with acids and acid anhydrides to yield polyesters. 2-Methyl-1,3-propanediol (MPDiol® Glycol) polyesters formed by the reaction of 2-methyl-1,3-propanediol with aromatic acids (isophthalic, terephthalic, and phthalic anhydride) result in hard, unsaturated polyester resins, which are used in applications such as bathroom countertops and tubs, as well

as boat manufacture. 2-Methyl-1,3-propanediol (MPDiol® Glycol) polyester polyols, which are formed by reaction with acids such as adipic acid, are used in polyurethane formulations for the coatings industry.

2.3 Exposure

No occupational exposure limits have been established for 2-methyl-1,3-propanediol (MPDiol® Glycol). Inhalation exposure is expected to be minimal due to its low vapor pressure. Workers involved in manufacture of 2-methyl-1,3-propanediol are encouraged to use eye and skin protection, although the irritation hazards of this substances are considered low. Some end-uses suggest a potential for dermal exposure.

3. Evaluation of OECD SIDS endpoints

3.1. Physical-Chemical Data

The physical-chemical properties of 2-methyl-1,3-propanediol (MPDiol® Glycol) have been the subject of a number of good quality guideline investigations, and include a full range of SIDS- and non-SIDS endpoints:

Table 2. Physical-Chemical Data

Property	Value	Rel †	Source
SIDS endpoints			
Melting point	<-54 °C	1	van Helvroit (1993a)
Boiling point	212 °C	1	van Helvroit (1993b)
Relative density	1.01	1	van Helvroit (1993c)
Water solubility	≥ 3000 mg/l at 25 °C	1	de Vries (1993a)
Vapor pressure	2.8 Pa at 25 °C	1	de Vries (1993b)
Log P_{ow}	0.24 at 20 °C	1	de Vries (1993c)
Non-SIDS endpoints			
Surface tension	72.2 mN/m at 20°C	1	van Helvroit (1993d)
Flash point	127 °C	1	van Helvroit (1993e)
Autoflammability	380 °C	1	van Helvroit (1993f)
Flammability	non-flammable	1	van Helvroit (1993g)

† Reliability according to Klimisch criteria.

Conclusion: Adequate information is available to characterize all physical-chemical endpoints. No testing is proposed.

3.2. Environmental Fate and Pathways

Results from MacKay Level I fugacity modeling indicate that environmental releases of 2-methyl-1,3-propanediol (MPDiol® Glycol) will partition mainly to water (Armstrong, 2003a; Rel 2). Results from the Level III program (Armstrong, 2003a; Rel 2) indicate that it will partition mostly in water (49.2%) and soil (47.4%) (assumes equal emission to air, water and soil). The half-life of MPDiol® Glycol for volatilization from a model river and a model lake is 101 and 1,102 days, respectively (Armstrong, 2003a)

The photodegradation potential of MPDiol® Glycol has been estimated using the AOPWin v1.90 subroutine present in the EPI Suite™ v3.10 program (Armstrong, 2003b; Rel 2). This indicates an overall hydroxyl radical rate constant of 11.4 x 10^{12} cm^3/molecule-sec, leading to a predicted atmospheric half-life of 11.2 hours.

Although not readily biodegradable based on the standard OECD Method 301 definition, MPDiol® Glycol has been shown to biodegrade in the presence of activated sludge, with $\leq$ 54% degradation to carbon dioxide over 28 days in a modified Sturm test (Bogers, 1993a; Rel 1) and $\leq$ 64% degradation over 28 days in a closed bottle test (Desmares-Koopmans, 1998; Rel 1).

It contains no groups susceptible to hydrolysis.

No measured BCF data were located, however a log P_{ow} value of 0.24 (see Section 3.1) and a predicted BCF of 3.16 (from BCFWin model; Armstrong (2003c), Rel 2) indicate that it is not likely to bioaccumulate in biological systems.

Conclusion: Adequate information is available to characterize all environmental endpoints. No testing is proposed.

3.3 Ecotoxicological Data

Acute toxicity data from guideline studies performed on organisms from three trophic levels demonstrate that 2-methyl-1,3-propanediol (MPDiol® Glycol) is not hazardous to aquatic species. This is supported by results from a guideline bacterial inhibition test (non-SIDS endpoint) and from guideline studies on higher plants (non-SIDS endpoint).

Table 3. Ecotoxicological Data

	Result (mg/l[§] or mg/kg dry wt soil[‡])	**Rel [†]**	**Source**
Aquatic organisms			
Cyprinus carpio (carp) 96 hr LC_{50}	>1000[§]	1	Bogers (1993b)
Daphnia magna (water flea), 48 hr EC_{50}	>1000[§]	1	Mitchell (1993)

Scenedesmus subpicatus (green alga), 72 hr IC_{50}	>1000[§]	1	Bogers (1993c)
Microorganisms			
Activated sludge, 30 min IC_{50}	>100[§]	1	Bogers (1993d)
Higher plants			
Latuca sativa (lettuce), EC_{50}	31-98[‡]	1	Lee and Aufderheide (2003)
Raphanus sativus (raddish) EC_{50}	811-1112[‡]	1	
Avena sativa (oats) EC_{50}	1112[‡]	1	

[†] Reliability according to Klimisch criteria.

Conclusion: Adequate guideline data are available to characterize the impact of 2-methyl-1,3-propanediol (MPDiol® Glycol) on environmental species. Results from these studies demonstrate low acute aquatic toxicity to algae, invertebrates and fish, and low toxicity to higher plants. No additional testing is proposed.

3.4 Toxicological Data

3.4.1. Acute toxicity

Results from modern guideline studies demonstrate that 2-methyl-1,3-propanediol (MPDiol® Glycol) in not acutely toxic in animals after inhalation, ingestion and skin contact.

Table 4. Acute Toxicity Data

Route	Species	Result	Comment	Rel [†]	Source
Inhalation LC_{50}	rat	>5100 mg/m^3	Limit test, aerosol	1	Muijser (1997)
Oral LD_{50}	rat	>5000 mg/kg bwt	Limit test	1	Cerven (1988a)
Dermal LD_{50}	rabbit	>2000 mg/kg bwt	Limit test	1	Cerven (1988b)

[†] Reliability according to Klimisch criteria.

3.4.2. Irritation and sensitization (non-SIDS endpoints)

2-Methyl-1,3-propanediol (MPDiol® Glycol) was not irritating to the skin or eye (Cerven (1988c,d), Rel 1) in animal tests (non-SIDS endpoints), nor were any untoward dermal responses observed in 25 human subjects with sensitive skin following a 14 day cumulative irritation test (Eisenberg (1997a), Rel 1).

While mild redness recorded in 3 of 20 guinea pigs challenged with 50% 2-methyl-1,3-propanediol (MPDiol® Glycol) as part of a maximization test (Daamen (1993), Rel 1) was suggestive of a mild sensitizing potential (non-SIDS endpoint), results from four human patch test studies (104 subjects) found no potential to induce or elicit allergic responses following 9 induction applications under occlusive (Eisenberg (1999a), Rel 1; Eisenberg (1999b), Rel 1) or semi-occlusive

(Eisenberg (1999c), Rel 1; Eisenberg (1999d), Rel 1) conditions. Findings from a fifth human patch test study (110 subjects; Eisenberg (1997b), Rel 1) were more ambiguous, with mild dermal responses noted in 4 individuals during the induction phase, and in 5 subjects upon challenge. Although reactions in one individual appeared consistent with an atopic state (i.e. reaction to 2-methyl-1,3-propanediol (MPDiol® Glycol) as well as propylene glycol and butylene glycol from day 2 of induction), it was not possible to determine whether irritation, allergy or an unrecognized atopic state was responsible for responses noted for the remainder. However, since no reactions were elicited during induction or challenge in >95% of the subjects from these 5 studies, it is clear that 2-methyl-1,3-propanediol (MPDiol® Glycol) is neither strongly irritating nor a potent sensitizer in the humans.

3.4.3 Repeated dose toxicity

Results from recent guideline sub-acute and sub-chronic toxicity studies are consistent with no adverse effects in male or female rats following repeated gavage administration at doses up to 1000 mg/kg bwt/day for 14 days (Reijnders (1993a), Rel 1) or 90 days (Reijnders (1993b), Rel 1).

3.4.4 Genetic toxicity

Results from modern, guideline *in vitro* genotoxicity tests demonstrate that 2-methyl-1,3-propanediol (MPDiol® Glycol) is not mutagenic in *Salmonella typhimurium* TA 1535 TA98, TA1535 or TA100 (±S9) or Chinese hamster V79 cells, nor does it induce chromosomal aberrations in human lymphocytes.

Table 5. Genetic Toxicity Data

End point	Test system	Conditions	Result	Rel[†]	Source
Gene mutation *in vitro*	Bacterial cells	TA1537, TA98, TA1535, TA100; ±S9, ≥ 5000µg/plate	Negative	1	van der Waart (1993a)
	Mammalian cells	V79 cells; ≥ 5000µg/ml	Negative	1	van der Waart (1993b)
Chromosomal aberrations *in vitro*	Mammalian cells	Human lymphocytes; ±S9, ≥ 5000µg/ml	Negative	1	van der Waart (1993c)

[†] Reliability according to Klimisch criteria.

3.4.5. Reproductive and Developmental Toxicity

3.4.5.1 Reproductive toxicity

No parental, neonatal or reproductive toxicity was observed following administration of 2-methyl-1,3-propanediol (MPDiol® Glycol) by gavage at doses

up to 1000 mg/kg bwt/day as part of a guideline 2-generation reproduction study (Nemec (2000), Rel 1). This lack of impact on the reproductive system was confirmed by an absence of microscopic changes lesions in gonadal tissue from male or female rats following sub-chronic gavage administration over 90 days (Reijnders (1993b), Rel 1).

3.4.5.2 Developmental toxicity / Teratogenicity

Results are available from two guideline developmental toxicity studies in the rat and one in the rabbit.

In the first study (Reijnders (1998), Rel 1) no maternal toxicity or alteration in fetal development was observed in female Wistar rats given 2-methyl-1,3-propanediol (MPDiol® Glycol) at $\leq$ 1000 mg/kg bwt/d by gavage on GD 0-20, however possible indications of embryotoxicity (reflected by a statistically significant increase in early absorptions) was noted in dams given 600 mg/kg bwt/day (6.1% per litter) or 1000 mg/kg bwt/day (5.9%) versus the controls (1.6%). Since the incidence of embryonic resorptions in the controls was at the lower end of the historic range, and since the percentage of embryo-fetal deaths reported for the 600 and 1000 mg/kg bwt/day groups appeared to have been skewed by an unusually high incidence in a single female in each dose level, the study was repeated. Interuterine growth and survival in this follow-up study (Nemec (1999), Rel 1) were unaffected after treatment with up to 1000 mg/kg bwt/d, and all other indicators (maternal performance, incidence of fetal malformations and variations) were unremarkable.

In the rabbit study (Nemec (2003), Rel 1), no maternal or fetal effects (including any treatment-related increase in variations or malformations) were observed when pregnant New Zealand white rabbits were given $\geq$1000 mg/kg 2-methyl-1,3-propanediol (MPDiol® Glycol) on GD 0-29.

Overall these guideline investigations demonstrate that 2-methyl-1,3-propanediol (MPDiol® Glycol) is not teratogenic or fetotoxic in rats or rabbits when administered by oral gavage during pregnancy at doses up to 1000 mg/kg bwt/d.

3.4.6 Metabolism (non-SIDS endpoint)

Results from in vitro metabolism studies indicate that 2-methyl-1,3-propanediol (MPDiol® Glycol) is a substrate for rat liver alcohol dehydrogenase (Boatman and Lantum (2003), Rel 1). *In vivo* toxicokinetic data (Boatman and Lantum (2003), Rel 1) demonstrate that it is rapidly metabolized and eliminated following gavage administration to the rat, primarily in urine (3-hydroxybutyric acid) and exhaled air (carbon dioxide).

Conclusion: Adequate data exist to demonstrate that 2-methyl-1,3-propanediol (MPDiol® Glycol) does not present a hazard after acute or repeated exposure.

The SIDS requirements for acute and repeat dose toxicity are therefore met, and no further testing is proposed.

Results from genotoxicity testing demonstrate it does not induce mutations or chromosomal aberrations *in vitro*. The SIDS requirements for genotoxicity testing are met, and no further testing is proposed.

It has been assessed for potential effects on fertility and development, but was without adverse impact in modern guideline studies. The SIDS requirements for reproductive toxicity testing are met, and no further testing is proposed.

4. Summary and Conclusion

There is adequate information available for 2-methyl-1,3-propanediol to meet the HPV Chemical Challenge requirements for physical-chemical and environmental fate data, ecotoxicology data, and the human health endpoints of acute toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity/teratogenicity, and genetic toxicity. The HPV Chemical Challenge Program requirements are met for 2-methyl-1,3-propanediol and no further testing is proposed.

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